

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

*The County of Summit, Ohio, et al. v.
Purdue Pharma L.P., et al.*
Case No. 1:18-op-45090 (N.D. Ohio)

*The County of Cuyahoga, Ohio, et al. v.
Purdue Pharma L.P., et al.*
Case No. 1:17-op-45004 (N.D. Ohio)

**MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster**

**REPLY TO MEMORANDUM OF LAW IN SUPPORT OF
MOTION FOR SUMMARY JUDGMENT ON PREEMPTION BY PHARMACY
DEFENDANTS, ABDC, CARDINAL HEALTH, AND MCKESSON (ECF 1867 & 2171)**

TABLE OF AUTHORITIES

Page(s)

Cases

Arizona v. United States,
567 U.S. 387 (2012).....1

Buckman Co. v. Plaintiffs’ Legal Comm.,
531 U.S. 341 (2001).....3

Gonzalez v. Raich,
545 U.S. 1 (2005).....1

Medtronic, Inc. v. Lohr,
518 U.S. 470 (1996).....2

McDaniel v. Upsher-Smith Labs.,
893 F.3d 941 (6th Cir. 2018)3

Statutes

Controlled Substances Act, 21 U.S.C. § 801, *et seq.* *passim*

Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*1

Other Authorities

71 Fed. Reg. 52,716 (Sept. 6, 2006)1

Plaintiffs' response fails to rebut the preemption of their claims against Pharmacy Defendants, ABDC, Cardinal Health, and McKesson¹ because those claims stand as an obstacle to and frustrate the purposes and objectives of the federal Controlled Substances Act, 21 U.S.C. § 801, *et seq.* ("CSA").

Plaintiffs assert that the Court has already "rejected this type of obstacle-preemption argument," Resp. at 1 (ECF 2171), but they cite the rejection of the argument that the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, preempts claims against the Manufacturers. That ruling has no bearing on this preemption motion, which demonstrates that a different statute (the CSA) preempts different claims that Plaintiffs raise against different defendants.

Plaintiffs do not deny that one purpose of the CSA is "to foster the beneficial use" of controlled substances, *Gonzalez v. Raich*, 545 U.S. 1, 24 (2005), and do not deny DEA's "obligation to ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound judgment of their physicians." Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,719-20 (Sept. 6, 2006). Plaintiffs' claims are thus preempted because the tort liability they seek to impose would frustrate the goal of that statute and "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399-400 (2012).

Pharmacy and Distributor Defendants do not, as Plaintiffs suggest (at 8 n.4), rely on field preemption. Their arguments rest solely on conflict preemption: that liability for the specific claims in this specific case asserted against these specific defendants (Pharmacy and Distributor

¹ "Pharmacy Defendants" are CVS Rx Services, Inc. and CVS Indiana, L.L.C., Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center, Walgreen Co. and Walgreen Eastern Co., HBC Service Company, an unincorporated operating division of Giant Eagle, Inc., Discount Drug Mart, and Walmart Inc. "Distributor Defendants" who join in this memorandum are AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation.

Defendants) would interfere with the full accomplishment of Congress's goal to ensure the availability of controlled substances in accordance with the medical judgment of physicians.

Pharmacy and Distributor Defendants' opening brief explained the nature of that interference. *See* Mot. 3-5 (ECF 1867). DEA established production quotas for opioid medications on an annual basis based on the legitimate medical need for those medications. Yet Plaintiffs, focusing only on the alleged harms from opioids, contend that Pharmacy and Distributor Defendants should have distributed 90% fewer pills than DEA authorized (and doctors prescribed). Plaintiffs' claims would interfere with Congress's purpose to ensure that the American people receive the medications prescribed by their physicians.

Plaintiffs' attempt to undermine that argument is not supported by the authority they cite. *Medtronic, Inc. v. Lohr*, for example, involves express preemption, not implied conflict preemption. 518 U.S. 470 (1996); *see id.* at 484 (“[W]e are presented with the task of interpreting a statutory provision that expressly pre-empt[s] state law.”). Nor do Plaintiffs deny that their theory of liability, in direct conflict with DEA's views, is “the fewer the opioids, and the sooner, the better.” Mot. at 5. Plaintiffs' reliance on the CSA's savings clause and *Wyeth v. Levine* is misplaced for the reasons set forth in Sections II and III of Small Distributors' preemption reply.

Plaintiffs appear to admit that their claims could survive preemption only if they “parallel Defendants' responsibilities under the CSA.” Resp. at 7. That is, Plaintiffs apparently recognize that state law cannot impose liability on conduct that complies with the CSA, so liability must “be premised in part on violation of the CSA.” Resp. at 2.² And state claims are preempted when they concern “compliance with federal regulations that are enforceable only by the Federal

² Separate and apart from preemption, Plaintiffs again mischaracterize the CSA and incorrectly describe “violations” of the CSA. *See* ECF 2159 (analyzing the provisions of the CSA and implementing regulations that do not impose the duties alleged by Plaintiffs to trigger liability).

Government.” *McDaniel v. Upsher-Smith Labs.*, 893 F.3d 941, 944-45 (6th Cir. 2018). Pharmacy and Distributor Defendants cited *McDaniel* in their motion (at 6), but Plaintiffs make no response.

Pharmacy and Distributor Defendants do not argue, as Plaintiffs assert (at 6), that Plaintiffs’ claims are preempted only because they “seek to police fraud against a federal agency.” Pharmacy and Distributor Defendants rely on the general principles of conflict preemption set forth in *Buckman* and elsewhere: that state tort liability is preempted where, as here, it would inevitably conflict with a “delicate balance of statutory objectives.” Mot. at 5 (quoting *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001)).

And contrary to Plaintiffs’ assertion (at 6-7), that their state law claims exist apart from federal law, they admit elsewhere that their claims are based on alleged violations of the federal statutory and regulatory framework. Even the terms they use in their opposition to this motion—“failure to maintain effective controls” and “suspicious” orders—come directly from federal statutes and regulations. See ECF 1887-1 at 1-2 (Plaintiffs seeking ruling by the court on CSA statutory and regulatory provisions because Plaintiffs assert that Defendants’ compliance with “the CSA” is relevant to several of their claims).

Plaintiffs never discuss general principles of conflict preemption, much less attempt to apply these principles to their claims. The closest they come is a conclusory statement buried in a footnote. See Resp. at 5 n.3 (“No such issue or obstacle exists in this case.”).

Plaintiffs apparently deny the existence of a conflict, but given the absence of any reasoned argument by Plaintiffs (as to, for example, how reducing by 90% the volume of distributed opioids could avoid interfering with filling prescriptions written by responsible physicians), there is little to which to reply and no basis to allow these claims to proceed. Plaintiffs’ claims conflict with the full accomplishment of Congress’s purposes and objectives of the CSA and are thus preempted.

Dated: August 16, 2019

Respectfully submitted,

/s/ Kaspar J. Stoffelmayr

Kaspar J. Stoffelmayr
BARTLIT BECK LLP
54 West Hubbard Street
Chicago, IL 60654
Phone: (312) 494-4400
Fax: (312) 494-4440
kaspar.stoffelmayr@bartlitbeck.com
Counsel for Walgreen Co. and Walgreen Eastern Co.

/s/ Eric R. Delinsky

Eric R. Delinsky
Alexandra W. Miller
ZUCKERMAN SPAEDER LLP
1800 M Street, NW
Suite 1000
Washington, DC 20036
Phone: (202) 778-1800
Fax: (202) 822-8106
edelinsky@zuckerman.com
smiller@zuckerman.com
Counsel for CVS Rx Services, Inc. and CVS Indiana, L.L.C.

/s/ Kelly A. Moore

Kelly A. Moore
MORGAN, LEWIS & BOCKIUS LLP
101 Park Avenue
New York, NY 10178
Phone: (212) 309-6612
Fax: (212) 309-6001
kelly.moore@morganlewis.com

/s/ Tina M. Tabacchi

Tina M. Tabacchi
Tara A. Fumerton
JONES DAY
77 West Wacker
Chicago, IL 60601
Phone: (312) 269-4335
Fax: (312) 782-8585
tmtabacchi@jonesday.com
tfumerton@jonesday.com
Counsel for Walmart Inc.

Elisa P. McEnroe
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103
Phone: (215) 963-5917
Fax: (215) 963-5001
elisa.mcenroe@morganlewis.com
Counsel for Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center

/s/ Timothy D. Johnson

Timothy D. Johnson
Gregory E. O'Brien
CAVITCH FAMILO & DURKIN, CO. LPA
Twentieth Floor
1300 East Ninth Street
Cleveland, OH 44114
Phone: (216) 621-7860
Fax: (216) 621-3415
tjohnson@cavitch.com
gobrien@cavitch.com
Counsel for Discount Drug Mart, Inc.

/s/ Geoffrey E. Hobart

Geoffrey E. Hobart
Mark H. Lynch
Christian J. Pistilli
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001
Tel: (202) 662-5281
ghobart@cov.com
mlynch@cov.com
cpistilli@cov.com
Counsel for Defendant McKesson Corporation

/s/ Enu Mainigi

Enu Mainigi
F. Lane Heard III
George A. Borden
Ashley W. Hardin
WILLIAMS & CONNOLLY LLP
725 Twelfth Street NW
Washington, DC 20005
Tel: (202) 434-5000
Fax: (202) 434-5029
emainigi@wc.com
lheard@wc.com
gborden@wc.com
ahardin@wc.com
Counsel for Defendant Cardinal Health, Inc.

/s/ Robert M. Barnes

Robert M. Barnes
Joshua A. Kobrin
MARCUS & SHAPIRA LLP
35th Floor, One Oxford Center
301 Grant Street
Pittsburgh, PA 15219
Phone: (412) 471-3490
Fax: (412) 391-8758
rbarnes@marcus-shapira.com
kobrin@marcus-shapira.com
Counsel for HBC Service Company

/s/ Robert A. Nicholas

Robert A. Nicholas
Shannon E. McClure
REED SMITH LLP
Three Logan Square
1717 Arch Street, Suite 3100
Philadelphia, PA 19103
Tel: (215) 851-8100
Fax: (215) 851-1420
rnicholas@reedsmith.com
smcclure@reedsmith.com
Counsel for Defendant AmerisourceBergen Drug Corporation